Amendment to the Claims

1. (currently amended) A formulation consisting of a therapeutically effective amount of a human growth hormone in an aqueous solution, a buffer that maintains the pH of the formulation at a pH of 5 to 7, a non-ionic polysorbate surfactant, a polymer stabilizer wherein said polymer stabilizer is a polyethylene glycol, methionine, and one or more optional excipients selected from the group consisting of a divalent cation present in a magnesium salt selected from the group consisting of magnesium hydroxide, magnesium chloride, magnesium sulfate, magnesium citrate, and magnesium edentate; a tonicity agent; and a preservative, wherein the formulation remains stable after at least one freezing and subsequent thawing event.

2. (original) The formulation of claim 1, wherein the human growth hormone is a recombinant form of human growth hormone.

3. (previously presented) The formulation of claim 2, wherein the recombinant form of human growth hormone is present in the formulation at a concentration of 0.1 mg/ml to 20 mg/ml.

4. (original) The formulation of claim 1, wherein the buffer is selected from the group consisting of sodium citrate, sodium edentate, sodium succinate, and histidine hydrochloride.

5. (currently amended) The formulation of claim 1, wherein the non-ionic polysorbate surfactant is present at a concentration of about 0.02% to about 10%.

6. (currently amended) The formulation of claim 1, wherein the non-ionic polysorbate surfactant is ~~a polysorbate~~ selected from the group consisting of polysorbate 20 and polysorbate 80.

7. (previously presented). The formulation of claim 1, wherein the polyethylene glycol is present at a concentration of about 0.25% or about 1%.

8. (previously presented) The formulation of claim 1, wherein the polyethylene glycol has a molecular weight in the range of about 3000 to about 20,000.

9. (original) The formulation of claim 1, wherein the tonicity agent is sorbitol.

10. (original) The formulation of claim 1, wherein the preservative is selected from the group consisting of phenol and benzyl alcohol.

11. (previously presented) A formulation consisting of about 0.1 mg/ml to about 20 mg/ml of a recombinant form of human growth hormone in an aqueous solution, a citrate or edentate buffer that maintains the formulation at a pH of about 5 to about 7, about 0.04% to about 5% (w/w) of a polysorbate surfactant, about 0.25% or about 1% (w/v) of polyethylene glycol, methionine, and one or more optional excipients selected from the group consisting of a sufficient concentration of sorbitol for the formulation to be approximately isotonic, magnesium chloride or magnesium hydroxide, and a preservative, wherein the formulation remains stable after at least one freeze thaw event.

12. (original) The formulation of claim 11, wherein the preservative is phenol or benzyl alcohol.

13. (previously presented) The formulation of claim 11, wherein at least about 90% of the recombinant form of human growth hormone remains in solution after exposure of the formulation to three or more freeze-thaw events.

14. (original) The formulation of claim 11 where the formulation is stable at about 2°C to about 8°C for at least 52 weeks.

15. (previously presented). The formulation of claim 14 wherein after 52 weeks at about 2°C to about 8°C at least one of

(i) total aggregate as measured by size exclusion HPLC is less than about 0.5%,

(ii) total deamidation as measured by anion exchange HPLC is less than about 7%, or

(iii) the recombinant form of human growth hormone recovery as measured by reverse phase HPLC is greater than or equal to 85%.